

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE CELEXA AND LEXAPRO) MDL DOCKET NO. 1736
PRODUCTS LIABILITY LITIGATION) ALL CASES

MEMORANDUM AND ORDER

The plaintiffs in this products liability Multi-District Litigation (MDL) allege that the antidepressants Celexa and Lexapro cause people to commit suicide. Defendant Forest makes, markets and sells these drugs. Out of the twelve cases remaining in this MDL, all but one involve adult decedents.¹ This matter is before me on Forest's motion to exclude plaintiffs' general causation expert, David Healy, M.D., from testifying when these remaining cases are returned to their transferor courts for trial [#623].² Forest asks me to find that this expert's opinions are so unreliable that they should be excluded from being tested by any cross-examination at trial, being weighed by any jury, or even limited in any respect by any trial judge.

In doing so, Forest relies heavily on the fact that, more than ten years ago, a district court excluded Dr. Healy's testimony and that decision was affirmed by

¹The rest of the cases were settled.

²None of these cases were filed in this Court so I will not be trying any of them.

the Tenth Circuit Court of Appeals. See Miller v. Pfizer, 196 F. Supp. 2d 1062 (D. Kan. 2002), aff'd, 356 F.3d 1326 (10th Cir. 2004). According to Forest, that should be the end of Dr. Healy's expert witness career in the United States.³ The Miller case involved a child who committed suicide after taking the antidepressant Zoloft.⁴ In that case, Dr. Healy opined that Zoloft induced suicidality. Ultimately (and subsequent to the Tenth Circuit's decision) the FDA concluded that "antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders."⁵ It could be

³Dr. Healy is Welsh and has served as an expert in this field both here and abroad.

⁴Zoloft, like Celexa and Lexapro, is in the class of antidepressant medications known as SSRIs (Selective Serotonin Reuptake Inhibitors). SSRIs operate by adjusting the manner in which the neurotransmitter serotonin is processed by brain cells. SSRIs are used to treat depression. Plaintiffs argue that all SSRIs can be treated alike, while Forest disagrees.

⁵This language is from the black-box warning label that the FDA requires on Lexapro and Celexa. In 2004, an advisory committee of the FDA recommended a "black box" warning of the emergence of suicidality in depressed adolescents. This recommendation came after FDA review and meta-analysis (a method for pooling results of multiple studies) of drug company adverse event report data from clinical trials. In 2006, an advisory committee of the FDA, the Psychopharmacological Drugs Advisory Committee (PDAC), was convened to consider whether antidepressants were associated with increased risk of suicidality in adults. "The PDAC evaluated a pooled analysis of 295 short-term trials covering more than 77,000 patients and eleven different antidepressants." Tucker v. Smithkline Beecham Corp., 701 F. Supp. 2d 1040, 1046 (S.D. Ind. 2010). Based on these reviews and resulting recommendations, the warning on all SSRIs now states:

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders. Anyone

argued, then, that Dr. Healy actually got it right in the Miller case and his opinions were ultimately validated by the FDA's own findings.

After presiding over this action for nearly seven years, reading the voluminous briefs and exhibits filed by both sides on this issue, and conducting an exhaustive search of cases on this topic (and on Dr. Healy's testimony specifically),⁶ I am not persuaded that Dr. Healy's opinions should be excluded from the underlying trials of these cases. I am not convinced that Dr. Healy's testimony should be excluded today simply because it was excluded more than a decade ago, particularly where the intervening science and the FDA have lent credence to his earlier opinions. More recent opinions, including one from the Honorable David F. Hamilton, Circuit Judge for the Seventh Circuit Court of Appeals sitting by designation in the district court, support my decision. See Tucker v. Smithkline Beecham Corp., 701 F. Supp. 2d 1040 (S.D. Ind. 2010).

considering the use of [Celexa/Lexapro] or any other antidepressant in a child adolescent or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior.

⁶I did not hold a hearing on this motion because the parties did not request one and I did not feel it was necessary for the resolution of this issue.

This Court serves as a gatekeeper only with regard to the admissibility of scientific evidence, and Dr. Healy's testimony passes the threshold test of admissibility. The weight of this testimony, however, will be decided by juries, after Dr. Healy is subjected to undoubtedly thorough cross-examination by Forest's able counsel.

Discussion

The opinion of a qualified expert witness is admissible if (1) it is based on sufficient facts or data, (2) it is the product of reliable principles and methods, and (3) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702. The expert's scientific, technical, or specialized knowledge must also "assist the trier of fact to understand the evidence or determine a fact in issue." Id. I must ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993). The function also serves "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152(1999).

"[T]he requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." Daubert, 509 U.S. at

590. The Supreme Court explained that evidentiary reliability means trustworthiness. Id. at 591 n. 9. “Proposed testimony must be supported by appropriate validation— i.e., ‘good grounds,’ based on what is known.” Id. at 590. “The standard for judging the evidentiary reliability of expert evidence is lower than the merits standard of correctness.” Kuhn v. Wyeth, Inc., 686 F.3d 618, 624-625 (8th Cir. 2012) (internal quotation marks and citation omitted). “Proponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered to determine which of several competing scientific theories has the best provenance.” Id. at 625 (internal quotation marks and citations omitted). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” Daubert, 509 U.S. at 596.

The Supreme Court identified in Daubert a number of factors that might assist the district court in determining the admissibility of expert evidence: (1) whether the theory or technique applied can be tested, (2) whether the theory or technique has been subject to peer review or publication, (3) the known or potential rate of error, and (4) whether it is accepted in the relevant discipline. Id. at 593–94. It instructed me to focus on “principles and methodology, not on the

conclusions that they generate.” Id. at 595. The Court later recognized that “conclusions and methodology are not entirely distinct from one another.” General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Expert evidence may be excluded if the court determines “that there is simply too great an analytical gap between the data and the opinion proffered.” Joiner, 522 U.S. at 146. “Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony. The rule clearly is one of admissibility rather than exclusion.” Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (internal quotation marks and citations omitted). “The exclusion of an expert’s opinion is proper only if it is so fundamentally unsupported that it can offer no assistance to the jury.” Wood v. Minn. Mining & Mfg. Co., 112 F.3d 306, 309 (8th Cir. 1997) (internal quotation marks and citation omitted).

Forest does not challenge the qualifications of Dr. Healy, who was described by Judge Hamilton as follows:

Dr. David Healy is a psychiatrist and academic neuropsychopharmacologist. He is an accomplished researcher and lecturer. He was awarded his doctorate based on his study and thesis on the subject of the serotonin reuptake system, and he has written many peer-reviewed medical journal articles concerning the SSRI class of drugs, including Paxil, and the risks and benefits of those drugs. He has authored or co-authored seventeen books in the field of mental health and psychiatric drugs, more than 140 peer-reviewed medical journal publications, and more than 160 non-peer reviewed articles,

and he has been invited to present his research and findings on over 200 occasions around the world. His credentials as an expert in this arena are undisputed.

Tucker, 701 F. Supp. 2d at 1047. I am equally impressed with Dr. Healy's credentials, and any suggestion that Dr. Healy is unqualified to testify based on his exclusion in the Miller case would be unwarranted and unfounded. Like Judge Hamilton I, too, am sufficiently assured that Dr. Healy "will testify with the same level of intellectual rigor that he would employ outside the courtroom." Tucker, 701 F. Supp. 2d at 1060.

Here, Dr. Healy opined to a reasonable degree of scientific and medical probability, and based on his training and experience and review of relevant literature, that Celexa and Lexapro can make individuals who may not have been likely to commit suicide before taking them, more likely to do so while on a course of treatment. He testified that Celexa and Lexapro can cause some people to experience akathisia, emotional dysregulation, and psychotic decompensation, which can result in suicide. In reaching this conclusion, Dr. Healy relied upon case reports and his own studies and calculations, including a review of healthy volunteer studies, and his meta-analysis of other available data. He also reviewed the mechanisms through which Celexa and Lexapro and other antidepressants

could trigger suicide, and he addressed the industry practice of ghostwriting scientific articles, which he said has led to exaggeration of the benefits of drugs and concealment of their risks. As in the Tucker case, Dr. Healy's opinion here is based on his ongoing review and analysis of studies relating to SSRIs generally, not Celexa and Lexapro specifically "because treatment emergent suicidality is a phenomenon common to the entire class of SSRI drugs." (Doc. # 636-13 at 10). Forest argues that Dr. Healy's opinions should be excluded because "individual SSRI compounds . . . are chemically distinct in structure and have different pharmacokinetic and pharmacologic properties." (Doc. # 624 at 6).

I agree with Judge Hamilton's conclusion on this issue and reach the same one here. See Tucker, 701 F. Supp. 2d at 1056-57. Although Celexa and Lexapro are unique chemical compounds, I am not persuaded that Dr. Healy's use of extrapolation or his reliance on data for SSRIs as a class renders his methodology in and of itself unreliable. "Notably here, although the FDA has recognized a variation in risk of suicidality amongst SSRIs, it has handled the drugs as a class, going so far as to . . . requir[e] . . . a class-wide label in May 2007." Id. In addition, "SSRIs are discussed as a class in a majority of the articles and studies relied on by the parties' experts . . ." Id. Given that SSRIs are commonly treated

as class by the scientific and medical communities,⁷ like Judge Hamilton I also find that Dr. Healy did not undermine the admissibility of his expert opinion by considering research regarding SSRIs generally in support of his conclusions about Celexa and Lexapro. Forest is certainly entitled to attack Dr. Healy's methods and conclusions with vigorous cross-examination and contrary evidence on this basis (including pointing out any differences between SSRIs), but Dr. Healy's opinion of general causation is not inadmissible for this reason.⁸

Next, Forest attacks Dr. Healy's opinions because they are based upon healthy volunteer studies.⁹ The healthy volunteer studies Dr. Healy relied on date back to the late 1950s, and none of them dealt with Celexa and Lexapro. However, as I have already found, I will not exclude Dr. Healy's opinions merely because he relied upon studies involving Reserpine, Paxil and Zoloft to reach his conclusions here. As the United States Supreme Court has recognized, “[t]rained experts commonly extrapolate from existing data.” Joiner, 522 U.S. at 146. Dr.

⁷Indeed, the FDA did so in 2004 as did the PDAC in 2006 when formulating the conclusions and recommendations upon which Forest so heavily relies.

⁸Forest also complains about the first section of Healy's report discussing the history of these two drugs, but I find no error in his inclusion of background information in his report. Healy is not required to present his findings in a certain format, and I would certainly never exclude an expert report on this basis. The motion to exclude on this basis is denied.

⁹Although I only address the discrete arguments and evidence Forest raised in its motion, I have reviewed the entirety of the record in reaching my decision.

Healy sets out the nature, limitations, and his interpretation of these studies in his expert report. (Doc. # 636-13 at 20-23). The basis of Dr. Healy's opinions, and his reliance on these studies to form his opinions, are certainly fodder for cross-examination, but I can find no basis for excluding Dr. Healy's opinions based on this evidence.

Dr. Healy also relies upon his own healthy volunteer study in support of his opinions, which he describes as follows:

This was a randomized double blind controlled study comparing reboxetine, a drug with no actions of the serotonin system, with Zoloft (and SSRI) and found that Zoloft induced significant suicidality in two of our healthy volunteers. The healthy volunteer group was comprised mainly of medical and nursing staff. A detailed description of the suicidality induced has been published in a peer-reviewed journal and presented at Royal College of Psychiatrists, British Association for Psychopharmacology and European College of Neuropsychopharmacology Meetings in the course of 2000.

The North Wales study demonstrated a similar profile of neuropsychiatric and other side effects, including obscure side effects such as dystonia or "pharyngitis," occurring in a similar ratio to company sponsored healthy volunteer studies. In general both Pfizer and SmithKline's studies and our study found a 40+% rate on average of subjects poorly tolerating SSRIs. We, however, were freer to explore further the consequences of some of these side effects. Our study makes it clear that subjects in company sponsored studies will almost certainly have been suicidal and perhaps even homicidal and indeed that the one in ten rate of suicide induction in our study was possibly low compared to some of these other studies.

(Doc. # 636-13 at 21). Forest's expert witness, John Concato, M.D., M.S., and

Ph.D., was appointed by the district court as an expert witness in Miller, and not surprisingly, levels some of the same criticisms at Dr. Healy's report as he did in that earlier case. In particular, Dr. Concato complains that Dr. Healy's study was subjective, influenced by Dr. Healy, and contradicts the FDA's study, which Forest admits is also a study of "essentially healthy volunteers." What this challenge ultimately amounts to, then, is that Forest believes that Dr. Healy did not rely on "the right" healthy volunteer studies in reaching his opinion. While these may certainly be valid points upon which to cross-examine Dr. Healy at trial, they are insufficient to exclude his testimony in limine. I cannot and will not exclude one expert's opinion simply because it disagrees with another's, even if that "other" expert is the FDA. Forest is free to argue its point of view to the jury — that the FDA and/or Dr. Concato are the "real" experts -- but there is no requirement that, to be admissible, an expert's opinion must agree with everything the FDA says.¹⁰ Moreover, Dr. Healy clearly was familiar with the FDA study and discussed it in his report, but he explained in his deposition and his report why he discounted the FDA's conclusions when analyzing the data. Forest may

¹⁰Interestingly, Dr. Healy critiques the drug company's studies on one of the same grounds advanced here — that the author's opinions (and their willingness to pay volunteers large sums of money) skewed the results. Dr. Healy also questions the reliability of the data provided to the FDA for similar reasons.

disagree with Dr. Healy's decision to discount the FDA's findings, but it is up to a jury, not me, to decide whether Dr. Healy's decision was a sound one.

Like Judge Hamilton, I am not troubled by the alleged limitations in Dr. Healy's studies, nor am I persuaded that they should be excluded simply because the district court in Miller found that they should.¹¹ Dr. Healy's opinions regarding SSRIs are certainly controversial. However, those opinions, and his North Wales study, have repeatedly been subject to professional debate and review through the peer-review and publication process. Additionally, a review of Dr. Healy's expert report reveals that he relied on other peer-review articles and studies addressing SSRIs and suicidality. While Forest may disagree with the methods and results of some of this research, they have been subjected to peer review and published for professional scientific evaluation.

Next, Forest criticizes Dr. Healy for "cherry picking" data to support his opinions. Forest points to data used by Dr. Healy taken from an article written in 2001 by Arif Khan and others to support his conclusion that the rate of suicide and suicidal acts in persons using Celexa versus a placebo was approximately 1.5.

¹¹Judge Hamilton does not even address the Miller case in his discussion of Dr. Healy's opinions. While there were undoubtedly good reasons why the district court appointed experts in Miller and ultimately decided to exclude Dr. Healy's opinion, I find the Miller case should be limited to its facts and not be applied here.

While Forest admits that Dr. Healy used the correct numbers from Dr. Khan's article, it argues that Dr. Healy's opinion should be excluded because the conclusions he drew from this data are contrary to that of Dr. Khan's. In his deposition, Dr. Healy explained why he chose to use this approach, why he discounted certain data considered by Dr. Khan, and why his conclusions about this data differed from that of Dr. Khan's. As stated above, “[t]rained experts commonly extrapolate from existing data.” Joiner, 522 U.S. at 146. There is no requirement that Dr. Healy reach the same conclusion as Dr. Kahn just because he relied on Dr. Kahn's data. Dr. Healy explained the bases for his opinions and his decision to omit certain data from his calculations, and this decision does not render his opinions inadmissible. These opinions have been subject to professional debate and review through the peer-review and publication process. As noted by Judge Hamilton when faced with a similar argument about Dr. Healy's testimony in Tucker, “[s]election and editing are inevitable, and choices of this sort are appropriate fodder for cross-examination.” Id. at 1059. To the extent Dr. Healy does not present the Kahn study and some of the other studies (and their conclusions) upon which his opinion is based in full, Forest should have the opportunity to do this at trial.

Forest makes the same argument with respect to Dr. Healy's discussion of

the FDA's findings on pages 33-34 of his report. Forest claims that Dr. Healy should not be able to use the FDA's data to support his opinion because the FDA reached the opposite conclusion when it analyzed the data. I reject this argument for the same reasons just discussed. Dr. Healy explained why his disagreed with the FDA's findings based on the data, and why he chose to discount certain data reported in this study.¹² Experts make these kinds of choices regularly when interpreting data, and Dr. Healy's opinions have been subject to professional debate and review through the peer-review and publication process. Again, Forest remains free to present the full findings and conclusions of the FDA at trial, and of course the underlying assumptions made by Dr. Healy in the formation of his opinions (including this one) are all subject to rigorous cross-examination.

Forest also complains about the format of Dr. Healy's report. In the section discussing evidence of general causation, Dr. Healy discusses mechanisms of suicide induction. According to Dr. Healy, "[m]y opinion is that this excess [of suicidal acts found in clinical trials on SSRIs] is produced by a series of mechanisms including an induction of agitation/akathisia, in addition to

¹²Dr. Healy believes that the FDA's research parameters were skewed to omit relevant data, and that the true risk of suicidality was much higher because the drug companies appeared to have submitted data "from studies that in my opinion were designed to confound this issue of suicidal behavior on their drug." (Doc. # 636-13 at 34).

emotional blunting and/or drug-induced psychotic decompensation. The mechanisms outlined below are the most commonly cited but not the exclusive candidates for leading to problems and in fact these mechanisms are likely to operate in combination rather than entirely independently.” (Doc. #636-13 at 35). Forest is a bit unclear on this point in its motion — at some points, it complains that Dr. Healy’s report is not explicitly set out using the “Bradford-Hill criteria,”¹³ in other parts of its motion Forest criticizes Dr. Healy for his “heavy dependence” on these criteria in the Miller case, and yet in other parts of its motion Forest claims not to know what analytic method Dr. Healy relied upon to assess general causation. Although the Bradford Hill criteria may be a tool for determining whether an epidemiological study establishes causation, see In re Neurontin, 612 F. Supp. 2d at 133, it is by no means required and “in the context of a general causation challenge, failure to satisfy the Bradford Hill criteria does not doom admission under Daubert.” Id. (citing In re Viagra Prods. Liab. Litig., 572 F. Supp. 2d 1071, 1081 (D. Minn. 2008)). Therefore, whether Dr. Healy did or did

¹³“Developed by Sir Bradford Hill in the 1960s, the criteria are nine factors which researchers often consider when judging whether an observed association is truly causal. The Bradford Hill criteria are: 1) strength of association; 2) consistency; 3) specificity of the association; 4) temporality; 5) dose-response curve; 6) biological plausibility; 7) coherence (with other knowledge); 8) experiment; and 9) analogy.” In re Neurontin Marketing, Sales Practices, and Prods. Liability Litig., 612 F. Supp. 2d 116, 132-33 (D. Mass. 2009) (internal citations omitted).

not use the Bradford Hill criteria will not determine the admissibility of his opinions, and Forest's motion to exclude on this basis will be denied.

Forest also challenges Dr. Healy's conclusion that these mechanisms produce an excess of suicidal acts. In support of his assertion that SSRIs produce agitation and akathisia, Dr. Healy relies on clinical trial dropout rates, drug company studies, FDA and other regulatory findings, as well as his own published and peer-reviewed research and writings. Forest argues this approach is suspect because Dr. Healy did not specifically consider Forest's patient narratives submitted to the FDA. Yet I have already ruled that Dr. Healy need not rely on Celexa/Lexapro specific data, so the mere fact that he did not consider Forest's submissions to the FDA does not render his opinions unreliable. On page 35 of his report Dr. Healy explains why the drug companies' definition of akathisia for these purposes is too restrictive and how clinical trial data has been manipulated to exclude akathisia as a reported event. On page 36 of his report, Dr. Healy cites a published article by E.J. Duncan and others entitled, "Akathisia and Exacerbation of Psychopathology: A Preliminary Report" as support for his conclusion that "akathisia can exacerbate psychopathology in general," and the Diagnostic and Statistical Manual IV as well as a published article written by R.M. Lane entitled, "SSRI-induced Extrapyramidal Side Effects and Akathisia: Implications for

Treatment” as support for his conclusion that there is a “consensus that [akathisia] can be linked to both suicide and violence.” Forest’s arguments that Dr. Healy’s opinion is “anecdotal at best” and not supported by “reliable scientific evidence” are unfounded. I understand that Forest may disagree with Dr. Healy regarding the link between SSRIs, akathisia and suicide, but his opinion and the evidence upon which he relies have been subject to professional debate and review through the peer-review and publication process. Again, Dr. Healy’s conclusions, and his underlying interpretation of data, remain fodder for cross-examination at trial.

Dr. Healy also opined that “SSRIs cause emotional blunting,” which makes “an individual less sensitive to the consequences of their actions than they would be in the normal course of events — making it possible to act without the fear of the consequences, or not to be inhibited by any moral consideration of the consequences of an action.” (Doc. # 636-13 at 36-37). Forest points out that Dr. Healy was unaware of one study where the authors concluded that this effect was not present in healthy elderly volunteers. Again, the mere fact that Dr. Healy did not consider one study about one segment of the population in the formation of his opinion in no way renders his testimony inadmissible. Of course, Forest may cross-examine Dr. Healy about this study and argue to the jury that his testimony deserves less credence because he did not consider it, but these types of arguments

go to the weight, not the admissibility, of Dr. Healy's testimony. As with his opinion regarding akathisia, Dr. Healy's conclusions regarding SSRIs and emotional blunting are supported by peer-reviewed, published articles. (Doc. # 636-13 at 36 n.37). While Dr. Healy's expert report may not explicitly state that there is an association between emotional blunting and suicide, Dr. Healy does opine that "the mechanisms [of which emotional blunting is one] are the most commonly cited but not the exclusive candidates for leading to problems and in fact these mechanisms are likely to operate in combination rather than entirely independently." (Doc. # 636-13 at 35). Therefore, I reject Forest's argument that Dr. Healy's testimony is inadmissible simply because he does not opine that emotional blunting independently leads to suicide.

Dr. Healy also opined that "a link between psychotic decompensation and suicide is part of standard psychiatric knowledge and finds a place in all textbooks, and more recently in the Summary of Product Characteristics for all major depressants." (Doc. # 636-13 at 37). In support of his conclusion, he relies on published articles written by himself and others, a published clinical study, and some unpublished data. While it would certainly be problematic if Dr. Healy's entire opinion on the link between psychiatric decompensation and SSRIs was based on unpublished data not produced to Forest, here that simply is not the case.

Dr. Healy refers to this unpublished data in passing and in addition to the other, numerous articles and studies which have been subject to professional debate and review through the peer-review and publication process. (Doc. # 636-13 at 37 n.38-41). Moreover, as stated above, Dr. Healy's testimony is that these mechanisms work in combination to produce "an excess of suicidal acts found in clinical trials on SSRIs." (Doc. # 636-13 at 35). Any arguable flaws in Dr. Healy's testimony on psychotic decompensation are most appropriately left to "[v]igorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof." Daubert, 509 U.S. at 596.

Next, Forest attacks Dr. Healy's testimony about the prevalence of "ghost writing" and its effect on the evidence.¹⁴ According to Dr. Healy, "the greatest determinant of the outcome of a published study lies in the identity of the sponsor. Companies in other words get the results they pay for." (Doc. # 636-12 at 38). In support of this assertion, Dr. Healy cites an article written by N. Freemantle and others entitled "Predictive Value of Pharmacological Activity for the Relative Efficacy of Antidepressant Drugs," published in the British Journal of Psychiatry in 2000, as well as a 2000 published article entitled "Publication Bias and the

¹⁴Dr. Healy refers to "ghost writing" as the practice of drug companies sponsoring studies to obtain favorable results and published data.

Integrity of Psychiatry Research” written by S.M. Gilbody and F. Song.

Forest does not challenge these published articles or contend that they do not support Dr. Healy’s opinion. Instead, Forest argues that Dr. Healy has no evidence that Forest has engaged in the practice of “ghost writing.” This is really just another way of challenging Dr. Healy’s extrapolation and reliance on data for SSRIs as a class. I have already rejected that challenge to the admissibility of Dr. Healy’s testimony, and I do so again for the same reasons.

In his supplemental declaration (Doc. # 636-37), Dr. Healy claims that one particular Celexa study was ghostwritten. Forest challenges Dr. Healy’s characterization of this study as being “ghostwritten” since one of the authors is listed a Forest employee. This type of challenge is what cross-examination is for and is not an appropriate basis upon which to exclude Dr. Healy’s testimony. Dr. Healy can explain his definition of “ghost writing” and the significance it plays in the formation of his opinion that Celexa and Lexapro induce suicide. Forest can then cross-examine Dr. Healy about the article mentioned in his supplemental declaration, the basis for his opinion regarding the significance of “ghost writing,” and the claimed absence of any data specific to Forest. A jury can then weigh this evidence along with the rest to determine the weight to be given Dr. Healy’s testimony. Forest’s motion to exclude Dr. Healy’s testimony on this basis will be

denied.

Finally, Forest claims that “Dr. Healy’s failure to address a large body of contrary epidemiological data and research is fatal to his reliability.” This is really just a restatement of Forest’s earlier argument that Dr. Healy ignored the FDA data, as well as its “cherry picking” argument made on a broader scale. I have previously rejected these arguments, and I do so again for the same reasons. As the Eighth Circuit held when rejecting a similar argument in Kuhn, “[t]here may be several studies supporting [Forest’s] contrary opinion, but it is not the province of the court to choose between the competing theories when both are supported by reliable scientific evidence.” 686 F.3d at 633.

To the extent Forest cites the opinion in Rimbert v. Eli Lilly and Co., Cause No. 06-0874 (D. N.M. July 21, 2009) [Doc. # 625-28], in an attempt to argue that Dr. Healy’s opinion should be excluded for failure to cite to any randomized clinical trials which are considered, epidemiologically speaking, to be the “gold standard” for determining statistical significance, I disagree with the Rimbert court that such studies are a prerequisite for admissibility in suicidality cases. Instead, I concur with Judge Hamilton’s discussion of this issue and adopt it here:

The study of suicide is rife with both ethical and practical difficulties. Meaningful studies require large numbers of participants. Thankfully, suicide is a rare act. Not only that, but to conduct a

placebo-controlled study, some patient-participants already at risk necessarily would be treated with a placebo. For practical and ethical reasons, suicidality itself has rarely if ever been studied in large, randomised placebo-controlled double-blind epidemiological studies.

Tucker, 701 F. Supp. 2d at 1060-61. Indeed, even “the trials upon which the FDA based its 2006 meta-analysis were not designed to specifically detect suicidality.” Id. at 1061. For these reasons, any motion to exclude Dr. Healy’s testimony on this basis must be denied.

By no means is there universal acceptance of Dr. Healy’s proposition that Celexa and Lexapro can induce suicide, and as Forest and its expert point out, there is a vigorous line of peer-reviewed, published research reaching the opposition conclusion. Yet, “Rule 702 permits testimony that is the product of competing principles or methods in the same field of expertise.” Tucker, 701 F. Supp. 2d at 1060. Although “not without controversy or arguable flaws, Dr. Healy’s opinion is sufficiently reliable to pass master under Daubert.” Id. Forest’s “arguments in opposition to the validity of Dr. Healy’s opinions are most appropriately left to ‘vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” Id. (quoting Daubert, 509 U.S. at 596).

Accordingly,

IT IS HEREBY ORDERED that defendant's motion to exclude the testimony of David Healy, M.D. [#623] is denied.



RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 4th day of March, 2013.